Dkt. 1567/70937-ZB/JPW/AG

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Jacob Bar-Tana

Serial No.: Not Yet Known

Filed : Herewith

For : METHODS FOR THE TREATMENT OF SYNDROME X USING XENOBIOTIC FATTY ACID COMPOUNDS

1185 Avenue of the Americas
New York, New York 10036
December 11, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450
Mail Stop: Patent Applications

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicant directs the Examiner's attention to the following disclosures, which are listed on Form PTO-1449 (**Exhibit A**).

1. U.S. Patent No. 4,634,795, issued on January 6, 1987 to Bar-Tana;

2. U.S. Patent No. 4,689,344, issued on August 25, 1987 to Bar-Tana;

3. U.S. Patent No. 4,711,896, issued on December 8, 1987 to Bar-Tana et al.;

4. U.S. Patent No. 4,954,487, issued on September 4, 1990 to

Cooper etal.;

5. U.S. Patent No. 5,502,226, issued on March 26, 1996 to Cho et al.;

6. U.S. Patent No. 5,502,077, issued on March 26, 1996 to Breivik et al.;

7. U.S. Patent No. 5,641,810, issued onJune 24, 1997 to Pill et al.;

8. U.S. Patent No. 6,303,653, issued on October 16, 2001 to Bar-Tana, attached hereto as **Exhibit 1**;

9. International PCT Application No. WO 98/30530;

10. International PCT Application No. WO 98/36745;

11. Israel Patent No. 119971;

12. Israel Patent No. 121165;

13. European Patent No. 0661049;

14. European Patent No. 0081930;

15. Bar-Tana et al., "Inhibition of lipid synthesis by β,β' tetramethyl-substituted C14-C22 α,ω dicarboxilic acids in the rat *in vivo*", J. Biol. Chem., 260:8404-8410 (1985);

16. Bar-Tana et al., "Hypolipidemic effect of β,β'-methyl-

substituted hexadecanedioic acid (MEDICA 16) in normal and nephrotic rats", J. Lipid Res., 29:431-441 (1988), attached hereto as **Exhibit 2**;

17. Bar-Tana et al., "Hypolipidemic effect of β,β'-methyl-substituted hexadecanedioic acid in normal and nephrotic rats", J. Lipid Res., 29:4431-441 (1998);

18. Bar-Tana et al., "Long chain dicarboxylic acids: Hypolipidemic, antiobesity and antidiabetic activity", New Antibiotic Drugs, (Eds. Bailey, C.J., Flatt P.R.). Smity-Torton and Comp. (1990);

19. Bar-Tana et al., "Synthesis, hypolipidemic and antidiabetogenic activities of β,β' tetra-substituted, long chain dioic acids", J. Med. Chem., 32:2072-2084 (1989);

20. Cave, W.T., "Dietary n-3 (omega-3) polyunsaturated fatty acid effects on animal tumorigenesis", FASEB J., 5:52160-2166 (1991);

21. Chin, J.P.F., Prost. Leuk. Essent. Fatty Acids, 50:211-222 (1994);

22. De-Fronzo et al., "Insulin resistance: a multifaceted syndrome responsible for NIDDM, obesity, hypertension, dyslipidemia and atherosclerotic cardiovascular disease", Diabetes Care, 3:173-194 (1991);

23. Frenkel et al., "The effect of β,β'-methyl-substituted

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24. Frenkel et al., "The hypochylomicronemic effect of β,β'-methyl-substituted hexadecanedioic acid is mediated by a decrease in apolipoprotein C-IIL", J. Biol. Chem., 263:8491-8497 (1988);

25. Grundy, S.M. & Denke, M.A., "Dietary influences on serum lipids and lipoproteins", J. Lipid Res., 31:1149-1172 (1990);

26. Hall et al., "The role of coenzyme A in the biotransformation of 2-arylpropionic acids", Chem. Biol. Interact., 90(3):235-252 (1994);

27. Hermesh et al., "Mitochondria uncoupling by a long chain fatty acyl analog", J. Biol. Chem., 273:3937-3942 (1997);

28. Hertz et al., "Mode of action of peroxisome proliferators as hypolipidemic drugs: suppression of apolipoprotein C-IIL", J. Biol. Chem., 270:13470-13475 (1995);

29. Hultin, M.B., "Fibrinogen and Factor VII as risk factors in vascular disease", Prog. Hemost. Thromb., 10:215-241 (1991), attached hereto as **Exhibit 3**;

30. Jeppesen et al., "Low triglycerides-high high-density lipoprotein cholesterol and risk of ischemic heart disease", Arch. Intern. Med., 161:361-366 (2001);.

31. Kahn-Rose et al., "Inhibition of lipid synthesis by β,β' tetramethyl-substituted C14-C22 α,ω dicarboxilic acids in cultured rat hepatocytes", J. Biol. Chem., 260:8411-8415 (1985);

32. Kalderon et al., "Tissue selective modulation of redox and phosphate potentials by β,β'-methyl-substituted hexadecanedioic acid", Endocrinology, 131:162-165 (1992);

33. Leff, T., Reue, K., Melian, A., Culver, H. & Breslow J.L., "A regulatory element in the ApoCIII promoter that directs hepatic specific transcription binds to proteins in expressing and nonexpressing cell types", J. Biol. Chem., 264:16132-16137 (1989);

34. Limatta et al., "Dietary Polyunsaturated Fatty Acids Interfere with the Insulin/Glucose Activation of I-type Pyruvate Kinase Gene Transcription", Molecular Endocrinology, 8:1147-1153 (1994);

35. Mayorek et al., Hypocholesterolemic effect of β, β'-methyl-substituted hexadecanedioic acid (MEDICA. 16) in obese Zucker rats in vivo", 289:911-917 (1993);

36. Mayorek et al., "Sensitization to insulin induced by β, β'-methyl-substituted hexadecanedioic acid (MEDICA 16) in obese Zucker rats *in vivo*", Diabetes, (1997);

37. Morris, M.C., Saks, F. & Rosner, B. Circulation 88, 523-533 (1993);

38. Neupert et al., "Effects of ibuprofen enantiomers and its coenzyme A thioesters on human prostaglandin endoperoxide synthases", BR. J. Pharmacol., 122(3):487-492 (1997);

39. Russel et al., "The hypolipidemic effect of β, β' tetramethylhexadecanedioic acid (MEDICA 16) in hyperlipidemic JCR:LA-corpulent rats", Arteriosclerosis and Thrombosis, 11:602-609 (1991);

40. Russell et al., "Inhibition of arherosclerosis and myocardial lesions in the JCR:LA-cp rat by β, β'-tetramethyl hexadecanedioic acid", Arterioscler. Thromb. Vasc. Biol., 15:918-923 (1991);

41. Sladek, F.M., "Liver Gene Expression" (eds. Tronche, F. & Yaniv, M.) pp. 207-230, R.G. Landes Co., Austin, TX (1994);

42. Sladek, F.M., Zhong, W.M., Lai, E. Darnell, J.E., Jr. Gene Dev., 4:233-2365 (1990);

43. Storlien, L.H. et al., "Fish oil prevents insulin resistance induced by high-fat feeding in rats", Science, 237:885-888 (1987);

44. The Metabolic and Inherited Bases of Inherited Disease (eds., Scriver, C.R., Beaudet, A.L., Sly, W.S., Valle, D.) Vol. II, Part 8, 1995 (McGraw-Hill, Inc.);

45. Tracy et al., "Metabolic inversion of (R)-ibuprofen-Coenzyme A", Drug Metabol. Dispos., 21(1):114-120 (1993);

46. Tzur et al., "Adipose reduction by β, β'-tetramyethyl-substituted hexadecanedioic acid (MEDICA 16)", Int. J. Obesity, 13:313-326 (1989);

47. Tzur et al., "The hypolipidemic antiobesity and hypoglycemic-hypoinsulinemic effects of β, β'-methyl-substituted hexadecanedioic acid in sand rats", Diabetes, 37:1618-1624 (1988);

48. Unger, R.H., "Lipotoxicity in the pathogenesis of obesity-dependent NIDDM. Genetic and clinical implications", Diabetes 44, 863-870 (1995); and

49. Yamagata, K. et al., "Mutations in hepatic nuclear factor alpha gene in maturity onset diabetes of the young (MODY 1)", Nature, 384:458-460 (1996).

The subject application is a continuation of and claims the benefit under 35 U.S.C. §120 of U.S. Serial No. 09/915,412, filed July 25, 2001, which is a divisional of U.S. Serial No. 09/104,880, filed June 25, 1998, now U.S. patent No. 6,303,653, issued on October 16, 2001, claiming priority of Israeli Application No. 121165, filed June 26, 1997.

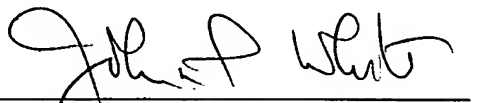
Above-listed references 1-3, 7, 9, 11, 12, 15, 17-19, 22-24, 27, 28, 31, 32, 34-36, 39-40 and 46-47 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed in connection with U.S. Serial No. 09/104,880, filed June 25, 1998. Above-listed references 4 and 5 were cited by the United States Patent and Trademark Office in an Office Action dated September 16, 2002 in connection with 09/915,412, issued July 25, 2001. Above-

listed references 6, 10, 13, 14, 26, 38 and 45 were submitted to and considered by the United States Patent and Trademark Office in a Supplemental Information Disclosure Statement filed on November 12, 2002 in connection with U.S. Serial No. 09/915,412, filed July 25, 2001. Accordingly, under 37 C.F.R. §1.98(d) copies of these references are not required to be provided to the United States Patent and Trademark Office, since they were previously submitted to or cited by the United States Patent and Trademark Office in an application relied upon for an earlier effective filing date under 35 U.S.C. §120. Copies of above-cited references 20, 21, 25, 29, 33, 37, 41-44 and 48-49 have not yet been submitted or considered by the U.S Patent Office. Applicant will submit copies of each of these references in a Supplemental Information Disclosure Statement as soon as such copies are obtained. Copies of above-cited references 8, 16 and 30 are submitted herewith, as Exhibit 1, 2 and 3, respectively.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

Pursuant to 37 C.F.R. §1.97(b)(3), no fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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	Applicant(s) Jacob Bar-Tana	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)	Filing Date Herewith	Group Art Unit

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	WO	98 30 53 0						
	WO	98 36 74 5						
	IS	11 99 71						
	IS	12 11 65						
	EPO	0 66 10 49						
	EPO	0 08 19 30						

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Bar-Tana et al., "Inhibition of lipid synthesis by β,β' tetramethyl-substituted C14-C22 α,ω dicarboxilic acids in the rat *in vivo*", J. Biol. Chem., 260:8404-8410 (1985);
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		Hermesh et al., ''Mitochondria uncoupling by a long chain fatty acyl analog'', J. Biol. Chem., 273:3937-3942 (1997);
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		The Metabolic and Inherited Bases of Inherited Disease (eds., Scriver, C.R., Beaudet, A.L., Sly, W.S., Valle, D.) Vol. II, Part 8, 1995 (McGraw-Hill, Inc.);

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		Tzur et al., ''Adipose reduction by , -tetramyethyl-substituted hexadecanedioic acid (MEDICA 16)'', Int. J. Obesity, 13:313-326 (1989);
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		Unger, R.H., ''Lipotoxicity in the pathogenesis of obesity-dependent NIDDM. Genetic and clinical implications'', Diabetes 44, 863-870 (1995); and
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